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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/252,710 06/02/94 RIVIERE I 8141113

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EXAMINER

FREDMAN, J

ART UNIT

PAPER NUMBER

1655

44

DATE MAILED:

10/26/00

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UNITED STATES DEPARTMENT OF COMMERCE
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/252,710
Filing Date: June 2, 1994
Appellant(s): Riviere et al

Paper No. 44
MAILED

OCT 25 2000

GROUP 2900

Dean H. Nakamura
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed August 21, 2000.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because claim 44 is identified as standing independent of claims 1-4, 6-31, 35-37, 42 and 43. However, claim 44 uses the term "consensus" without basis in the specification and is rejected for the same reasons as each of the other claims.

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(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-4, 6-31, 35-37 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP 608.04(a) states "Matter not in the original specification, claims, or drawings is usually new matter. Depending on circumstances such as the adequacy of the original disclosure, the addition of inherent characteristics such as chemical or physical properties, a new structural formula or a new use may be new matter. See *Ex parte Vander Wal*, et al. , 1956 C.D. 11; 705 O.G. 5 (physical properties), *Ex parte Fox* , 1960 C.D. 28; 761 O.G. 906 (new formula) and *Ex parte Ayers*, et al. , 108 USPQ 444 (new use)."

Here, the new limitation to a "consensus splice site" as found in claims 1, 10 and 21, lacks basis in the original specification. The appellant cites the use of a splice site from the MOV-9 vector on page 29 of the specification in support of this broad term, but since many different consensus splice sites may exist, built around the basic GT-AG site, this term represents a broad

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term which is not supported by the narrower disclosure of the specification. In the absence of any specific support, this term represents new matter.

(11) *Response to Argument*

Appellant first points to locations in the specification which relate to the splice donor and acceptor site, such as page 15, lines 3 and 4, and which, presumably, appellant relies upon for basis. The relevant portion of page 15, lines 2-4 read “preferably the partial gag coding sequence comprises a splice donor site and is linked upstream from a splice acceptor site.”

Appellant relies upon *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) for the proposition that an *ipsis verbis* disclosure of the claimed subject material is not required for descriptive support. First, in *Alton*, a declaration which purported to characterize the specification and which was not given sufficient weight was at issue. Here, there is no declaration whatsoever. Thus, the evidentiary position between these cases is very different. Second, in *Alton*, the issue was whether a single description of two different elements, a deletion and a mutation, which both had descriptive support, were separable. Here, there is a single element which is simply lacking any descriptive support whatsoever.

Appellant then argues that the examiner has not made a *prima facie* case. As MPEP 2163.02 notes “If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed

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subject matter is not described in that application.” Here, a factual inquiry shows that the term “consensus” does not appear in the specification as filed and this term is an addition or departure from that specification. MPEP 2163.04 notes with regard to the burden on the examiner in order to make a prima facie case that “(A) identify the claim limitation not described; and (B) provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed.” The rejection reiterated above identifies the claim limitation not described, the term “consensus” with regard to splice sites, and provided reasons why selection of either a specific splice site, the MOV-9 site, or the simple term “splice acceptor site”, fails to provide descriptive support for a “consensus” splice site. Thus, a prima facie case has been made, and appellant fails to provide evidence which rebuts this case.

In order to understand the difference between a simple splice donor or acceptor site and a “consensus” site, it is necessary to understand what molecular biology defines as a consensus sequence. In Walker et al, The Language of Biotechnology, A Dictionary of Terms, “consensus sequence” is defined as “The sequence that gives the most common nucleotide at each position in cases where there are a number of minor variations between nucleotide sequences that have the same function (e.g., promoters).” Thus, the question of whether the specification describes a “consensus sequence” depends upon two factual inquiries, i) whether MOV-9 is, in fact, inherently a “consensus sequence” and ii) whether this inherent property can properly serve as support for the broader term.

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Appellant then argues that "consensus" sequence is a term defined by the art and that the ordinary artisan would recognize that a "splice acceptor site" could include a consensus sequence. This argument is not persuasive for because the argument misstates the inquiry involved in determination of new matter. As the court noted in *The Gentry Gallery, Inc. v. The Berkline Corp.*, 134 F.3d 1473, 1479-80, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998), "claims may be no broader than the supporting disclosure." This same logic applies here, where the claims supporting disclosure does not support the broader "consensus" language. Further, it is certain that, based upon the sequences chosen, multiple different consensus splice sites could be created. In fact, the various articles cited by appellant in this and earlier responses expressly disclose multiple different consensus splice sites. Thus, if appellant's argument was accepted, the next question would be, what "consensus" sequence, none of which are even remotely disclosed by the specification, are embodied by this term. Would appellant be permitted to have any known or later discovered consensus sequence, or limited to prior art consensus sequences, or limited to the ones cited by appellant? This argument points out the incoherency of the idea that the routine artisan can support this term, because the question then becomes, which routine artisan "consensus" sequences fall within the scope desired by appellant. This question cannot be answered by the specification because it is completely silent on this issue and this is the essence of new matter.

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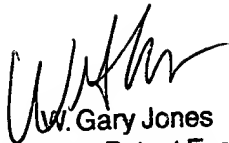
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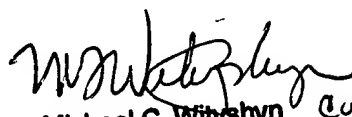
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

JNF
October 23, 2000


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